

By way of present amendment, Claims 52 and 60 have been amended; Claim 37 has been cancelled; and claims 61 and 62 have been added. Claims 1-36 have been withdrawn pursuant to a restriction requirement.

Thus, as of the present amendment, Claims 1-36 and 38-62 are pending in the application and claims 38-62 are under consideration.

Response to Office Action Paragraphs 2-4

Claim Rejection Under 35 U.S.C. §112

In the Office Action the Examiner rejected Claims 38-51 under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated that Claims 38-51 recite the limitation "mizoribine" for which there is insufficient basis for this limitation and that independent Claim 60 (from which Claims 38-51 depend) discloses the release of methylprednisolone and does not mention the release of mizoribine.

By way of the present amendment, Claim 60 has been amended to correct this inadvertent mistake and methylprednisolone has been replaced with mizoribine.

Applicants respectfully submit that the present amendment obviates this rejection and request withdrawal of this rejection.

Response to Office Action Paragraphs 5-6

Claim Rejection Under Double Patenting

In the Office Action the Examiner provisionally rejected Claims 52-60 under the judicially created doctrine of obviousness-type double, over the copending Application No. 09/782,804.

Applicants respectfully acknowledge this rejection and will address this rejection once the claims are otherwise in condition for allowance.

Response to Office Action Paragraphs 7-9

Claim Rejection Under 35 U.S.C. §102(b)

In the Office Action the Examiner rejected Claims 60 and 38-51 under 35 U.S.C. §102(b) as being anticipated by Domb et al. (USPN 5,512,055), and Claims 37, 52-54 and 57-59 as being anticipated by Gregory et al. (USPN 5,283,257).

In rejecting Claims 60 and 38-51, the Examiner noted that “Domb et al. disclose a stent with polymeric coatings with methylprednisolone as is claimed.”

By way of the present amendment, Claim 60 has been amended to correct an inadvertent mistake (namely, typing methylprednisolone instead of mizoribine). Claim 60 as amended recites, among other things: “... releasing mizoribine from the prosthesis into the blood vessel so as to inhibit smooth muscle cell proliferation.” Support for this amendment can be found in the application as originally filed.

In contrast to the present invention, Domb et al. does not teach or suggest the release of mizoribine from a vascular prosthesis.

Applicants submit that Claim 60, as amended, and those claims depending directly or indirectly therefrom, are not anticipated by or obvious in view of Domb et al., and that they are patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claims 60 and 38-51.

In rejecting Claims 37, 52-54, and 57-59, the Examiner noted that Gregory et al. discloses a method for treating hyperproliferative vascular disease by administering MPA (mycophenolic acid), and mizoribine (referencing the abstract and column 3 lines 44-52 and column 4 lines 24-31).

Gregory et al. is directed to the use of MPA in preventing hyperproliferative vascular disease. Gregory et al. discloses in vivo and in vitro examples of the effect of administration of MPA, cyclosporine (CsA), FK 506, rapamycin (RPM), and MPA in combination with RPM on the intimal thickening. All of the limited examples in Gregory et al. were limited to systemic administration of the drugs. Although the description makes a reference to other ways for administering MPA,

e.g., impregnation of a vascular stent with MPA, Gregory et al. provides no teaching or enablement whatsoever as to a method for inhibiting restenosis using mizoribine, and more particularly releasing mizoribine from a stent.

Gregory et al. at most provides a speculative reference as to the potential use of mizoribine in prevention of hyperproliferative vascular disease based on its classification as an IMP-DH inhibitor.

In addition, Claims 52 and 60 have been amended to further recite "... implanting a vascular prosthesis comprising a scaffold having means thereon for releasing mizoribine in the blood vessel; and releasing mizoribine from the prosthesis into the blood vessel so as to inhibit smooth muscle cell proliferation."

In contrast to the present invention, Gregory et al. does not teach or suggest a prosthesis comprising a scaffold having means thereon for releasing mizoribine.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Associates v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Applicants respectfully request withdrawal of this rejection and the allowance of Claim 52 and all claims depending directly or indirectly therefrom.

Response to Office Action Paragraph 10

Allowable Subject Matter

Applicants note with appreciation the indication that Claims 55 and 56 will be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

By way of present amendment, New Claims 61 and 62 are respectively claims'55 and 56 rewritten in independent form to include all the limitations of the base claim are thus in condition for allowance.

Applicants respectfully request the allowance of new Claims 61 and 62.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please cancel claim 37

52. (Amended) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:

implanting a vascular prosthesis comprising a scaffold having means thereon for releasing mizoribine in the blood vessel; and

releasing mizoribine and at least one other substance in addition to mizoribine from the prosthesis when implanted in the blood vessel so as to inhibit smooth muscle cell proliferation.

60. (Amended) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:

implanting a vascular prosthesis comprising a scaffold having means thereon for releasing mizoribine in the blood vessel; and

releasing mizoribine [**methyprednisolone**] from the prosthesis into the blood vessel so as to inhibit smooth muscle cell proliferation.

61. (New) A method for inhibiting restenosis in a blood vessel following recanalization of the blood vessel, said method comprising:

implanting a vascular prosthesis in the blood vessel; and

releasing mizoribine and at least one other substance in addition to mizoribine from the prosthesis when implanted in the blood vessel, wherein the at least one other substance is methylprednisolone.

62. (New) A method as in claim 61, wherein mizoribine is released within a time period of 1 day to 45 days and methylprednisolone is released within a time period of 2 days to 3 months.